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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,732	11/22/2006	**Jae-Kyu Jung**	22578-006US1 080.US2.PCT	9799

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EXAMINER	
SOLOLA, TAOFIQ A	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
05/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,732	JUNG ET AL.	
	Examiner	Art Unit	
	Taofiq A. Solola	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *26 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-5,7-35 and 48* is/are pending in the application.

4a) Of the above claim(s) *1-5,7-26 and 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *27-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-5, 7-35, 48 are pending in this application.

Claims 1-5, 7-26, 48 are drawn to non-elected invention.

Claims 6, 36-47 are deleted.

Restriction Requirement

The election of group VIII, with traverse in the Paper filed 3/26/08, is hereby acknowledged. The traversal is on the basis set forth in the Paper. The restriction of groups I-VII is hereby withdrawn due to the amendment of the claims, and group VIII is being examined commensurate in scope therewith. Applicant further elects dyslipidemia as specific disease for examination in group VIII.

The restriction of groups VIII-IX, though traversed, there are no specific basis for the traversal. The restriction is till deemed proper and therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-35, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification lacks adequate support for the claims. The terms hydrate and solvate are not defined in the specification so as to ascertain the structures of the compounds included and/or excluded by the terms. Specifically, the number of moles of water that forms the hydrate

and/or solvate is not disclosed in the specification. By deleting the terms the rejection would be overcome.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-35, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23-24 are drawn specific enantiomers of the compounds in the claim 1. However, enantiomers or racemate is not claimed in 1. By deleting the claims the rejection would be overcome.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-35, are rejected under 35 U.S.C. 102(b) as being anticipated by Jirkovsky et al., J. Med. Chem., (1982), Vol. 25(10), pp. 1154-6.

Jirkovsky et al. disclose compounds in the attached abstract (claims 1-5, 7, 11, 17, 25) wherein R1 is H or methyl, R2 is H, R3 is phenyl (aryl) or 4-chlorophenyl, R4 is methyl or isopropyl, and their composition for treating hyperlipidemia (dyslipidemia). See the abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27-35, are rejected under 35 U.S.C. 102(b) as being 103(a) as being unpatentable over Jirkovsky et al., J. Med. Chem., (1982), Vol. 25(10), pp. 1154-6.

Applicant claims method of using compounds of formula 1 for treating dyslipidemia.

Determination of the scope and content of the prior art (MPEP ∋2141.01)

Jirkovsky et al., teach compounds in the attached abstract (claims 1-5, 7, 11, 17, 25) wherein R1 is H or methyl, R2 is H, R3 is phenyl (aryl) or 4-chlorophenyl (substituted phenyl), R4 is methyl or isopropyl, and their composition for treating hyperlipidemia (dyslipidemia). See the abstract.

Ascertainment of the difference between the prior art and the claims (MPEP ∋2141.02)

The difference between the instant invention and that of Jirkovsky et al., is that applicant claims alkyl at position R4 while the prior art teaches methyl at the position. In other words applicant replaced H with alkyl in the prior art compound.

Also, some compounds in claims 21-22 have Br, FI or I instead of Cl as substituent on the phenyl, and are position isomers of the compounds by Jirkovsky et al. The enantiomers are in claims 23-24 instead of racemate by the prior art.

Finding of prima facie obviousness---rational and motivation (MPEP ∋2142.2413)

However, H and alkyl are art recognized equivalents. *In re Lincoln*, 53 USPQ 40 (CCPA, 1942); *In re Druey*, 319 F.2d 237, 138 USPQ 39 (CCPA, 1963); *In re Lohr*, 317 F.2d 388, 137

USPQ 548 (CCPA, 1963); *In re Hoehsema*, 399 F.2d 269, 158 USPQ 598 (CCPA, 1968); *In re Wood*, 582 F.2d 638, 199 USPQ 137 (CCPA, 1978); *In re Hoke*, 560 F.2d 436, 195 USPQ 148 (CCPA, 1977); *Ex parte Fauque*, 121 USPQ 425 (POBA, 1954); *Ex parte Henkel*, 130 USPQ 474, (POBA, 1960).

Enantiomers are obvious from their racemate. *In re Adamson,* 125, USPQ 233 (1960). When the difference between compounds is the length of a carbon chain such are adjacent homologs. However, adjacent homologs are prima facie obvious. *In re Henze*, 85 USPQ 261 (1950).

A novel and useful compound, which is an isomer of a compound of prior art, is prima facie obvious. *In re Norris,* 84 USPQ 458 (1950). Therefore, the instant invention is prima facie obvious from the teaching of Jirkovsky et al. One of ordinary skill in the art would have known to use position isomers, replace H with alkyl, replace one halogen with another and/or use adjacent homologs at the time the invention was made. The motivation is from knowing that H and alkyl are equivalents, that halogens are replaceable, and that adjacent homologs and isomers would have similar biological properties.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, 1625

May 10, 2008